K112682

MAR 19 2012

B. 510(k) SUMMARY (as required by 21 CFR 807.92)

Metha Hip System
February 29, 2012

COMPANY: Aesculap Implant Systems, LLC
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 3005673311

CONTACT: Kathy A. Racosky
610-984-9291 (phone)
610-791-6882 (fax)

TRADE NAME: Metha

COMMON NAME: Metha Hip System

CLASSIFICATION NAME: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented
Prosthesis, Hip, Semi-Constrained, Uncemented, Metal/Polymer, Non-Porous, Calcium-Phosphate
Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented

REGULATION NUMBER: 888.3360, 888.3353, 888.3353

PRODUCT CODE: LWJ, MEH, LZO

SUBSTANTIAL EQUIVALENCE
Aesculap Implant Systems, LLC believes that the Metha Hip Systems are substantially equivalent to:

- Metha Hip Systems (K080584 & K071916)
- MAYO Conservative Hip Prosthesis (K030733 & K061461)
- Profemur Hip System Modular Necks (K091423)

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DEVICE DESCRIPTION

The Metha Hip Systems are a short stem design with either a single piece stem or a modular stem/neck option. Both of these hip systems share common heads in either CoCr or Ceramic. The stem is manufactured from titanium alloy. The proximal area of the femoral stem is plasma sprayed (Plasmapore®) with a secondary coating of Calcium Phosphate (µ-CaP®). This stem is designed for cementless use only. The acetabular cup that is cleared for use with the two systems is referred to as PlasmaCup and is a UHMWPE insert with a Titanium plasmaspray shell.

INDICATIONS FOR USE

The Metha Hip System (uncemented, press-fit fixation) is intended to replace a hip joint.

The device is intended for:

- skeletally mature individuals undergoing primary surgery for total hip replacement
- patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur.
- patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis
- patients suffering from disability due to previous fusion
- patients with acute femoral neck fractures

TECHNOLIGICAL CHARACTERISTICS(compared to Predicate(s))

As is established in this submission, the Aesculap Implant Systems Metha Hip Systems are a short stem design with either a single piece stem or a modular stem/neck option that are substantially equivalent to other predicate devices cleared by FDA. The subject device is shown to be substantially equivalent and has the same technological characteristics to its predicate devices through comparison in design, intended use, material composition, function and range of sizes.

PERFORMANCE DATA

As recommended by the FDA Guidance for Industry and FDA Staff - Non-clinical Information for Femoral Stem Prostheses was performed to demonstrate that the Metha Hip System is substantially equivalent to other predicate devices. The following testing was performed to support substantial equivalence:

- Fatigue testing per ISO 7206-4 and ASTM F2068-03

Testing demonstrated that the device is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 19 2012

Aesculap Implant Systems, LLC.
% Ms. Kathy A. Racosky
Senior Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K112682
Trade/Device Name: Metha Hip System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, MEH, LWJ
Dated: March 9, 2012
Received: March 12, 2012

Dear Ms. Rocosky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

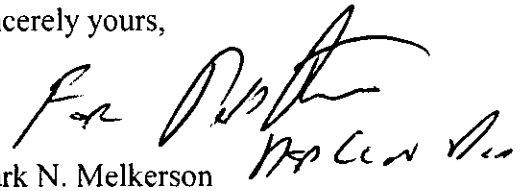
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K112682

Device Name: Metha Hip System

Indications for Use:

The Metha Hip System (uncemented, press-fit fixation) is intended to replace a hip joint.

The device is intended for:

- skeletally mature individuals undergoing primary surgery for total hip replacement
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- patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis
- patients suffering from disability due to previous fusion
- patients with acute femoral neck fractures

Prescription Use ___X___ and/or Over-the-Counter Use _____

(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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